

Adjuvant giredestrant sets a new standard in early-stage breast cancer

Market Event Summary

Adjuvant giredestrant improves iDFS in early-stage breast cancer

Event

- **Adjuvant giredestrant significantly reduced the risk of invasive disease recurrence or death** compared with **standard of care (SOC) endocrine therapy**, highlighting its potential to redefine SOC for early-stage HR-positive / HER2-negative breast cancer.
- **The pivotal Phase 3 lidERA trial** (n = 4,170) assessed giredestrant versus SOC endocrine therapy in medium- or high-risk stage I-III HR-positive / HER2-negative early breast cancer. The key outcomes at the primary analysis are summarized in the table.

Key endpoints	Primary analysis outcome, giredestrant vs. SOC (median follow-up: 32.3 months)
Invasive disease-free survival (primary endpoint)	<ul style="list-style-type: none">• 30% reduction in the risk of invasive recurrence or death (hazard ratio 0.70, P = 0.0014)• 3-year rates: 92.4% vs. 89.6%
Distant recurrence-free interval	<ul style="list-style-type: none">• 31% reduction in the risk of distant metastatic recurrence (hazard ratio 0.69)• 3-year rates: 94.4% vs. 92.1%
Overall survival	<ul style="list-style-type: none">• Positive trend for giredestrant (hazard ratio 0.79, P = 0.1863) but OS data are immature
Safety	<ul style="list-style-type: none">• Lower rate of treatment discontinuation due to adverse events (5.3% vs. 8.2%)

Background

- **Five years of endocrine therapy** is the SOC adjuvant treatment for HR-positive / HER2-negative early-stage breast cancer.
- Approximately **one-third of patients** with early-stage breast cancer **experience disease recurrence** during or after completion of adjuvant endocrine therapy. **Safety and tolerability challenges** result in treatment interruptions or discontinuations, which can compromise therapeutic efficacy and increase the risk of recurrence.
- Despite recent successes in HR-positive / HER2-negative metastatic breast cancer, **no oral SERD had demonstrated benefit in early-stage disease** before these results.

Clarivate's takeaways



Expected positioning in breast cancer

If approved as adjuvant therapy, giredestrant will benefit from its broad applicability in medium- or high-risk disease, favorable tolerability, and ease of use (oral formulation).



Blockbuster potential

HR-positive / HER2-negative is the largest breast cancer segment and represents approximately 70% of all breast cancer incident cases.

Giredestrant is the first oral SERD to demonstrate a clinically significant adjuvant benefit. Supported by strong Phase 3 lidERA clinical data and extended treatment duration, it is well-positioned to achieve blockbuster status.



Constraints

CDK4/6 inhibitor plus endocrine therapy regimens will be key competitors, particularly in high-risk patients. Limited long-term data and cost may further restrict broad adoption upon approval.

About the author



Glenda Walker, Ph.D.

Senior Healthcare Research & Data Analyst

DRG Commercial Solutions

Dr. Walker has more than 12 years' experience in the pharmaceutical field. She has authored thought-leadership articles covering a broad range of pharmaceutical-industry-relevant topics and therapeutic areas, including the flagship Drugs to Watch article. She holds a Ph.D. in cell biology and genetics from the University of Manchester and was a Wellcome postdoctoral fellow at the University College London Institute of Healthy Ageing.

Clarivate coverage of breast cancer

- Breast Cancer | [Disease Landscape & Forecast | G7](#)
- Breast Cancer | [Current Treatment: Physician Insights | US](#), exploring the current prescribing trends among medical oncologists treating breast cancer
- Breast Cancer | [Current Treatment: Treatment Sequencing | US](#), presenting surveyed medical oncologists' most frequent treatment sequences for breast cancer
- [Metastatic HR-positive / HER2-negative Breast Cancer | Unmet Need](#)



Think forward™

Have a question?

lsh.support@clarivate.com
clarivate.com

+1 215 386 0100 (U.S.)

+44 (0) 20 7433 4000 (Europe)

About Clarivate

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit [clarivate.com](https://www.clarivate.com)

© 2025 Clarivate. All rights reserved

Clarivate and its logo, as well as all other trademarks used herein are trademarks of their respective owners and used under license.